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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/019,048

12/27/2001

Ernst Heinz

0093/000032

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02/03/2010

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EXAMINER

HIBBERT, CATHERINE S

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

02/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/019,048	Applicant(s) HEINZ ET AL.	
	Examiner CATHERINE HIBBERT	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,8-10 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 8-10 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's submission filed on 4 November 2009 has been entered.

Claims 2-5, 7, 11-12 and 14-21 are cancelled. Claims 1, 6, 8-10 and 13 are pending and under examination in this action. This action is NON-FINAL because some of the new grounds of rejection were not necessitated by amendment.

Response to Amendment

All objections/rejections to cancelled claims 2-3 are moot.

All objections/rejections not repeated herein are withdrawn.

Priority

Priority for the claimed invention is granted back to the filing date of the 09/347,531 application, filed 7/6/1999.

Response to Arguments-rejections under 35 U.S.C. §102(a) and §103(a)

The rejection of Claims 1 and 8-9 under 35 U.S.C. 102(a) as being anticipated by Girke et al. (Plant J., July, 1998) and the rejection of Claims 6 and 10 under 35 U.S.C. 103(a) as being unpatentable over Girke et al in further view of Napier et al are **maintained** and restated below. The rejection of independent Claim 13 is **withdrawn** based on Applicants persuasive arguments and the Declaration under 1.131 filed on 19 February, 2008. The rejection of cancelled Claims 2-3 is moot. Examiner notes for clarity of the record that Claim 13 is newly rejected below under new grounds of rejection.

Applicants traverse the rejections under 35 U.S.C. §102(a) and §103(a) by pointing to the Declaration under 37 CFR §1.131 filed on 19 February, 2008. Applicants argue that said Declaration “included facts establishing that the presently claimed invention was reduced to

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practice prior to July 27, 1998, thus antedating the Girke reference" and therefore rendering the rejections under 35 U.S.C. §102(a) and §103(a) moot.

Examiner has carefully considered the Declaration under 37 CFR §1.131 filed on 19 February, 2008 in view of Applicants remarks but finds that the Declaration is not sufficient to overcome the art of record as it pertains to the instant Claims 1, 8-9, 6 and 10 but that the Declaration is sufficient to overcome the art as it pertains to the independent Claim 13 which is drawn to an isolated nucleic acid comprising SEQ ID NO:1. First, the Declaration on page 2 (part 4) states that the "above-mentioned invention was conceived and reduced to practice no later than 1997" and attests on page 2 (part 5) that the "present invention" was made prior to the Girke publication (published on 27 July 1998). However, the instant set of claims are different than the inventions referred to in parts 4 and 5 of the Declaration and Applicant has not pointed out how the evidence presented in the Declaration under 1.131 filed 19 February 2008 is related to the instant claims, as written. Secondly, the scope of the evidence presented in the Doctoral thesis is not commensurate with the scope of the instantly claimed invention. For example, the instant claims read not only on SEQ ID NO:1 and 2 but also on a genus of nucleic acid molecules derived from SEQ ID NO:1 (e.g. see instant Claims 1 and 9, part b) and also on a genus of nucleic acid molecules derived from SEQ ID NO:1 wherein said molecules encode polypeptides having at least 95% homology at the amino acid level with SEQ ID NO:2 (e.g. see instant Claims 1 and 9, part c) having A6-desaturase activity and use of said sequences to prepare an unsaturated fatty acid in any plant or any yeast. The evidence presented in the Thesis involves expression of SEQ ID NO:1 in *S. cerevisiae* cells and in *P. patens*. No disclosure is provided concerning expression of any of the genus of nucleic acids encompassed within the

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instant claims in any other type of yeast or plant. No disclosure is provided of any transgenic organisms other than the specific *S. cerevisiae* yeast cells transformed with SEQ ID NO:1. No disclosure is provided in the Thesis concerning other derivatives of SEQ ID NO:1. Since the evidence presented in the 1.131 Declaration is insufficient to show that applicants were in possession of the claimed subject matter, said Declaration is insufficient to overcome the outstanding 35 USC 102(a)/103(a) rejections which are restated just below.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 8-9 STAND rejected under 35 U.S.C. 102(a) as being anticipated by Girke et al. (**Plant J., July, 1998, Vol. 15(1), pp. 39-48**, of record in the IDS; and referenced by Score Report result for SEQ ID NO:1 and NO:2) for reasons of record and presented herein.

Currently amended Claims 1 and 8 are drawn to a process of preparing an unsaturated fatty acid, which comprises introducing, into an organism being a yeast or plant, at least one isolated nucleic acid sequence encoding a polypeptide having $\Delta 6$ -desaturase activity, selected from the group consisting of:

(a) A nucleic acid sequence having the sequence shown in SEQ ID NO:1,

(b) nucleic acid sequences which, as a result of the degeneracy of the genetic code, are derived from the sequence shown in SEQ ID NO:1, and

(c) a derivative of the nucleic acid sequence shown in SEQ ID NO:1 which encodes the polypeptide with the amino acid sequence shown in SEQ ID NO:2 or a polypeptide having at least 95% homology at the amino acid level said polypeptide still having Δ 6-desaturase catalytic activity,

and culturing the organism to express the polypeptide and isolating the unsaturated fatty acid from the organism.

Currently amended Claim 9 reads on a transgenic yeast comprising an isolated nucleic acid sequence comprising the sequence shown in SEQ ID NO:1.

Girke et al. teach identification and expression of a Δ 6-desaturase (D6D) from *P. patens* (PPDES6) (e.g., Abstract). The reference teaches that the cDNA for PPDES6 is 2012 bp, i.e., SEQ ID NO: 1. (e.g., p. 40, col. 1, last full paragraph) and see Score Report “Result 2” which shows a nucleic acid sequence with 100% identity to the instant SEQ ID NO:1 which is to the 2012 bp mRNA sequence encoding the delta6-acyl-lipid desaturase of *P. patens* submitted as pertaining to the Girke et al journal article published July 1998 (Plant J. 15, pages 39-48).

In addition, the reference teaches expression of PPDES6 in the yeast strain *S. cerevisiae*. (e.g., p. 45, col. 2, ¶ 3). Furthermore, expression of PPDES6 in the cells (i.e., cultured cells) produces concentrations of unsaturated fatty acids that are at least 1 or 5%, whereby to measure the concentration of said fatty acids, each would inherently have to be isolated from the yeast cells. (e.g., p. 45, col. 1, Table 1).

35 USC 103(a) Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 and 10 STAND rejected under 35 U.S.C. 103(a) as being unpatentable over Girke et al., as applied to Claims 1 and 8-9 above, in further view of Napier et al (of record).

Girke et al. teach expression of PPDES6 (instant SEQ ID NO:1) in yeast and yeast cells as described above.

The Girke et al. reference does not explicitly teach expression of PPDES6 in plants or an oil crop. However, the reference implies that the desaturase, such as PPDES6 isolated from moss, is a good source for producing a wider variety of polyunsaturated fatty acids (UFAs). (e.g., p. 39, under "Introduction"). In any event, utilization of D6Ds to modify the lipid composition in oilseed crop was a primary focus in the art at the time of invention. For example, Napier et al. discuss utilizing desaturases from different sources for producing a wider variety and beneficial

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UFAs. (e.g., Abstract; p. 123). More particularly, the reference explicitly notes that the D6D isolated from *P. patens* is another D6D, in the same vein as producing fatty acids in transgenic oilseed crop. (e.g., p. 125, ¶ 1). The primary thrust of Napier et al is that expression of desaturases in transgenic plants will lead to production of 'designer oil[s]' in said plants so as to meet the demands of the pharmaceutical and chemical industry. (e.g., p. 126, last paragraph).

Therefore, it would have been obvious to utilize the PPDES6 desaturase as taught by Girke in plants or oilseed crop. One would have been motivated to make such transgenic plants and to produce UFAs therein, so as to utilize PPDES6, with the benefit of extending the range of beneficial designer oils or UFAs produced. Furthermore, given the level of skill at the time of invention, there would have been a reasonable expectation of success in producing UFAs in a plant, transformed with PPDES6.

New grounds of rejection under 35 USC 102 and 35 USC 103(a)

Claims 1, 8-9 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Thomas Girke in "Functional characterization of a novel desaturase from *P. patens*", Doctoral thesis, May, 1998, entered in the online catalog on September 8, 1998 (made of record in the 1.131 Declaration filed 19 February 2008).

Claims are described above. The Dissertation of T. Girke discloses an isolated nucleic acid comprising SEQ ID NO:1 and a method of introducing the nucleic acid into the yeast strain *S. cerevisiae*, for expressing the delta6-desaturase for production and isolation of an unsaturated

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fatty acid (e.g. see 1.131 Declaration filed 19 February 2008 submitted by Applicant) and therefore anticipates the limitations of the instant Claims 1, 8-9 and 13.

Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Score Report “Result 2” submitted as a direct submission by author T. Girke on 19 December 1997 (University Hamburg). The Score Report “Result 2” shows a nucleic acid sequence with 100% identity to the instant SEQ ID NO:1 which is to the 2012 bp mRNA sequence encoding the delta6-acyl-lipid desaturase of *P. patens*.

Claims 1, 6, 8-10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reddy and Thomas in “Expression of a cyanobacterial delta6-desaturase gene results in gamma-linolenic acid production in transgenic plants” (Nature Biotechnology, Vol. 14, May 1996; pages 639-642) in view of the Score Report “Result 2” submitted as a direct submission by author T. Girke on 19 December 1997 (University Hamburg) (above). Reddy and Thomas teach a method of using oil seed crops transfected with a cyanobacterial delta6-desaturase gene to produce and isolate unsaturated fatty acids (e.g. gamma-linolenic acid) from transgenic plants (e.g. see title and abstract).

Reddy and Thomas fail to teach using the delta6-desaturase gene from *P. patens* (i.e. SEQ ID NO:1).

The Score Report “Result 2” shows the nucleic acid sequence with 100% identity to the instant SEQ ID NO:1 which is to the 2012 bp mRNA sequence encoding the delta6-acyl-lipid desaturase of *P. patens* was available as a direct submission in 1997.

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It would have been obvious to one of ordinary skill in the art of transgenic plants to have substituted the use of the *P. patens* delta6-acyl-lipid desaturase for the cyanobacterial delta6-desaturase of Reddy and Thomas because Reddy and Thomas teach that it is within the ordinary skill of the art to insert transgenes into plant cells and one would have been motivated to do so to produce delta6-desaturase to produce and isolate unsaturated fatty acids from transgenic oil crop plants and because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention and Girke disclosed the delta6-acyl-lipid desaturase of *P. patens* was available as a direct submission in 1997. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE HIBBERT, whose telephone number is (571)270-3053. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/NANCY VOGEL/

Primary Examiner, Art Unit 1636

Catherine Hibbert

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